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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,412	12/17/2003	Michelle D. Hines	SC65U-US	8911

60723 7590 04/18/2007

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/738,412	HINES ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *28-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 3/28/2007 is acknowledged. The traversal is on the ground(s) that there is no undue or serious burden placed on the Examiner to search the inventions of Groups I, II and III. This is not found persuasive because as stated in the original Election/Restriction, Inventions I and II are related as product and process of use and the method of Group II (improving the appearance of skin) can be accomplished with another materially different product such as tretinoin or benzoyl peroxide. In addition, Invention I differs from Invention III in that the method of Invention III (treatment or prevention of advanced glycation endproduct related conditions comprising administration of an effective amount of an advanced glycation endproduct inhibiting or cleaving thiazole compound can be accomplished with another materially different product such as NSAIDS. Further, Inventions II and III are unrelated due to the fact that the method of Invention II is drawn to improving the appearance of skin with an effective amount of the advanced glycation endproduct inhibiting or cleaving thiazole compound and a completely different method of treating or preventing advanced glycation endproduct related conditions, which include diabetes, rheumatoid arthritis etc.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-27 are being examined as they read on a cosmetic or pharmaceutical composition, the intended use of the composition is not given patentable weight.

Claim Rejections – 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 2-amino-4,5-dimethylthiazole to inhibit advanced glycation endproduct (AGE), does not reasonably provide enablement for all pharmaceutical compositions of the formula in claim 1 to inhibit advanced glycation endproduct. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims 1-27 are drawn to a cosmetic or pharmaceutical composition comprising an AGE inhibiting or cleaving compound of the formula in claim 1.

(2) The relative skill of those in the art: The relative skill of those in the art is high.

(3) The breadth of the claims: Claims 1-27 embraces a cosmetic or pharmaceutical composition comprised of an AGE inhibiting or cleaving compound of the formula in claim 1.

(4) The amount of guidance or direction presented: In the instant case, working examples are presented for the efficacy of 2-amino-4,5-dimethylthiazole in inhibiting AGE formation in the specification on pages 10-11. Studies in control tubes and plates were performed in which it was shown that 2-amino-4,5-dimethylthiazole inhibited AGE formation. However, there are a lack of working examples presented in the specification as filed showing that all compounds of the formula in claim 1 inhibit AGE formation. Note that lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP § 2164.

(5) The presence or absence of working examples: Applicant provides working examples for AGE inhibition by 2-amino-4,5-dimethylthiazole. However, applicant does not provide any working examples for AGE inhibition by all compounds of the formula in claim 1.

(6) The quantitation of experimentation necessary: Claims 1-27 read on a cosmetic or pharmaceutical composition comprised of AGE inhibiting or cleaving compound of the formula in claim 1. As discussed above, the specification provides examples for AGE inhibition by 2-amino-4,5-dimethylthiazole, but the specification fails to provide sufficient support for AGE inhibition by all compounds of the formula in claim 1. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections – 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13, 15-18, 21, 23 rejected under 35 U.S.C. 102(b) as being anticipated by Wagle et al. (US Pg-Pub 2002/0022622).

Wagle et al. teach pharmaceutical compositions that are identical to the pharmaceutical composition of the present invention. In particular, Formula I corresponds to the compounds of the present invention (i.e., 2-aminothiazole, 4,5-

dimethylthiazole; paragraphs 0004, 0016-0028 and 0249 and claim 1). More particularly it meets the limitation of 2-amino-4,5-dimethylthiazole as cited in claim 13 when J is sulfur, R^a and R^b are alkyl and R^c is amino (see Formula I in claim 1). The compositions of the invention typically include a vehicle (further meeting the limitation of claim 23; paragraph 0278).

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-12, 14, 19-20, 22, 24-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Wagle et al. (US Pg-Pubs 2002/0022622) as applied to claims 1-9, 13, 15-18, 21 and 23 in the above rejection and further in view of Gould (Int J Pharmaceutics, 33 (1986) 201-217).

Wagle et al. teach compositions identical to the composition of the present invention as discussed above.

Wagle et al. do not teach the compositions as a salt or the weight percentages of the composition.

Gould et al. teaches that salt formation provides a means of altering the physicochemical and resultant biological characteristics of a drug without modifying its

chemical structure and teaches that hydrochloride is an FDA-approved commercially marketed salt (see Table 1).

Furthermore, it is obvious to vary and/or optimize the amount of 2-amino-4,5-dimethylthiazol provided in the composition, according to the guidance provided by Wagle et al., to provide a composition having the desired properties such as the desired percentages that will effectively treat a disease or condition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would be obvious to one or ordinary skill in the art at the time of invention to combine the teachings of Wagle et al. with Gould et al. because Gould et al. teach that hydrochloride is an FDA-approved commercially marketed salt. One would be motivated to combine the references and add the hydrochloride salt to 2-amino-4,5-dimethylthiazol in an effort to stabilize the compound.

Conclusion

No claims are allowed.

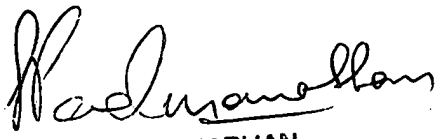
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER